

Risk-Based Approach to Conformity Assessment

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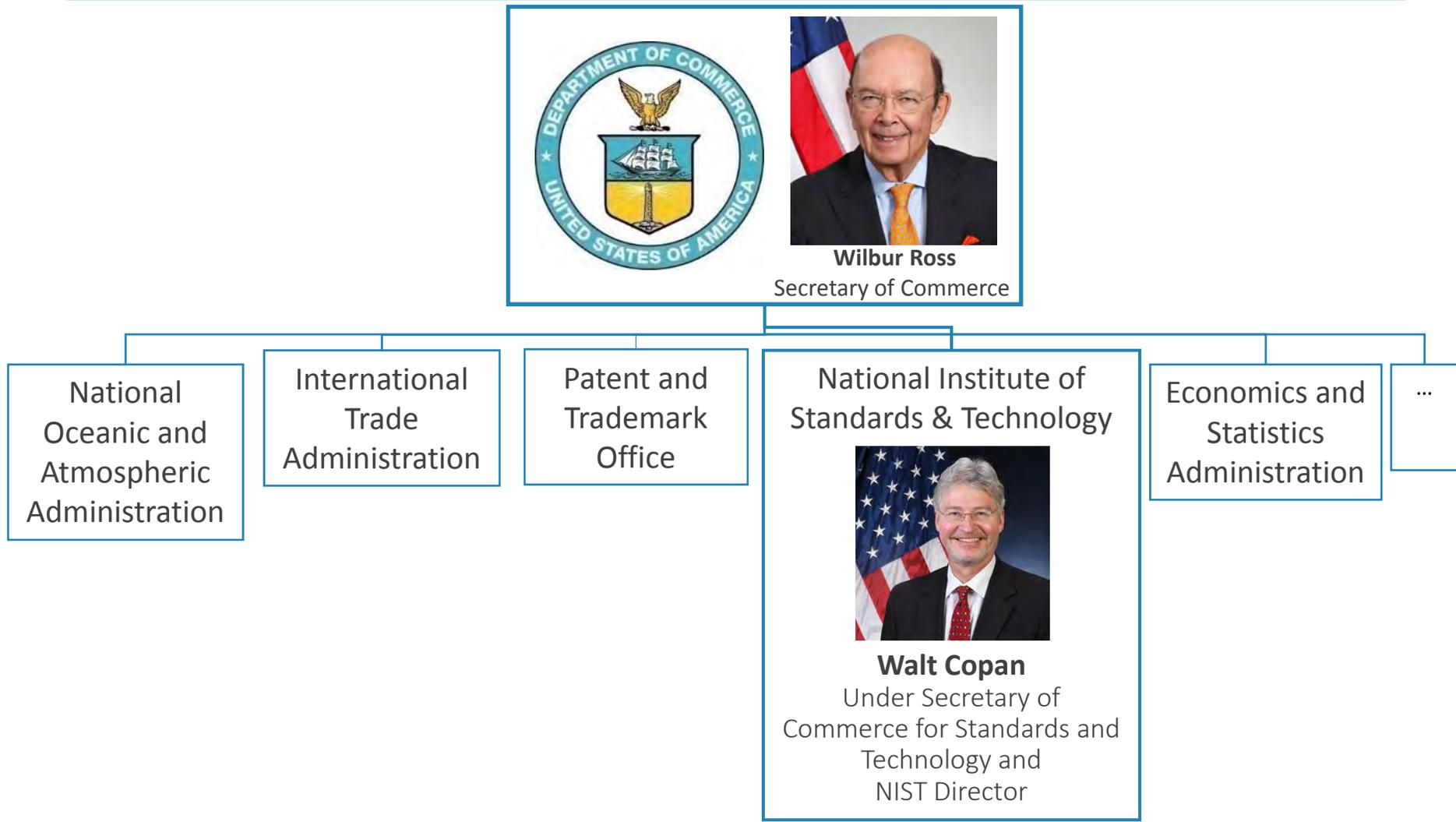
Agenda

1. Overview of the National Institute for Standard and Technology (NIST)
 - NIST's role in commerce
2. Mitigation of the Risk from counterfeit / fake consumer products with standards

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 - NIST's role in Quality Infrastructure
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Where NIST Fits Within Commerce



National Institute of Standards and Technology

Promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

Measurement science

Create the experimental and theoretical tools – methods, metrics, instruments, and data – that enable innovation

Standards

Develop and disseminate physical standards and provide technical expertise to standards that enables comparison, ensure interoperability, and supports commerce

Technology

Drive innovation through knowledge dissemination and public-private partnerships that bridge the gap between discovery and the marketplace

Measurements and Standards are Critical to Innovation & Trade

If you know how to measure something, you can design it, improve it, and compare it.

NIST measurement science provides the foundation for innovation in every industry and economic sector.

Up to 92% of U.S. exports affected by standards / technical regulations

NIST: Who We Are and What We Do

NIST is a world-class scientific and technical agency uniquely focused on driving innovation and economic competitiveness through:



- **a world-leading scientific research program** – measurement, technology, and standards solutions to our stakeholders



- **a Manufacturing Extension Partnership** – focused on strengthening our nation's small and medium manufacturers --- thousands of small manufacturers in 50 states and Puerto Rico rely on the NIST MEP program for hands-on technical and business assistance to assist them in competing in the global marketplace



- **an Advanced Manufacturing National Program Office** – facilitating expansion of a nationwide network of Manufacturing Innovation Institutes (14)
- **a Baldrige Performance Excellence Program** – used to assess performance excellence in the nation's companies and organizations. Criteria from the BPEP are recognized, utilized, and emulated around the world

NIST's Strengths

- NIST is recognized as having deep technical excellence
- NIST is seen as an uncompromising measurement science laboratory, the best in the world
- NIST is known for its neutrality, providing unbiased results
- NIST is industry-focused, providing extensive ties to companies, consortia and associations
- NIST is non-regulatory and doesn't make (but can inform) policy, allowing open discussions with stakeholders



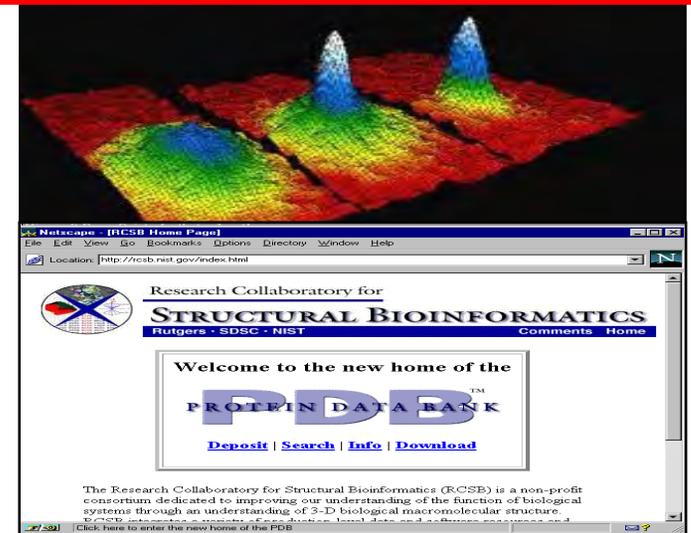
NIST Laboratories

- **Measurement Research**
>>2,200 publications/year
- **Standard Reference Data**
>65 types available
>20 on-line databases
virtually all NIST databases available free on-line

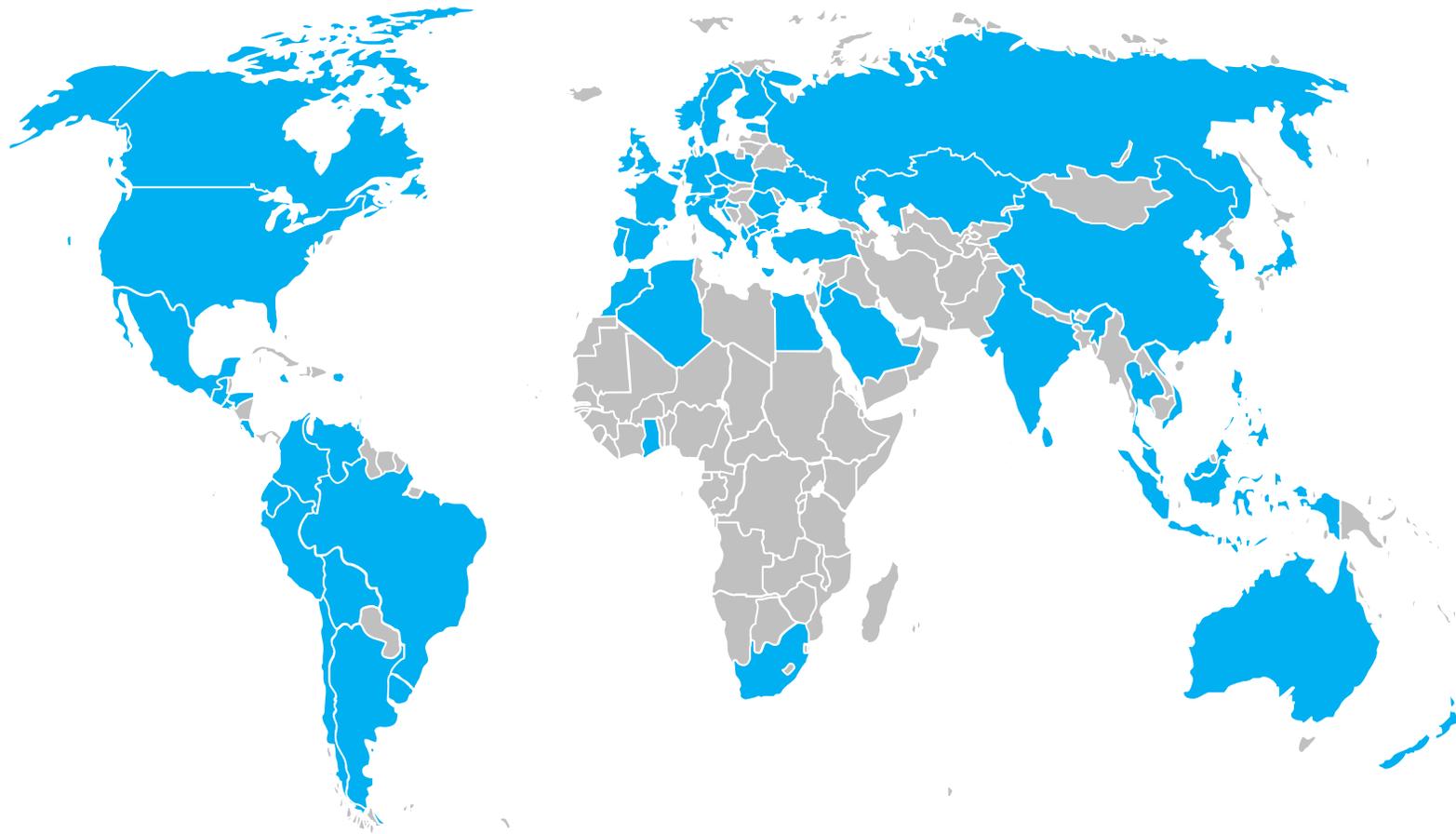
Standard Reference Materials

- >1,300 types available*
- >32,000 units sold/year*

- **Calibrations and Tests**
>3,000 items/year

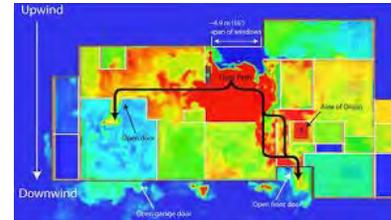


Technical Inquiries from Over 80 Countries in 3 Years



NIST's Unique Role in Documentary Standards

- Legislated Roles:
 - NIST coordinates standards policy among federal agencies
 - NIST Director is President's principal advisor on standards
- 400+ NIST technical staff in 100+ standard committees
- Leadership in international standards bodies like ASTM, IEEE, ISO, IEC



NIST studies of fire behavior led to changes in U.S. building codes, which saved lives



Standards and conformity assessment requirements for public safety comms equipment is transforming emergency response

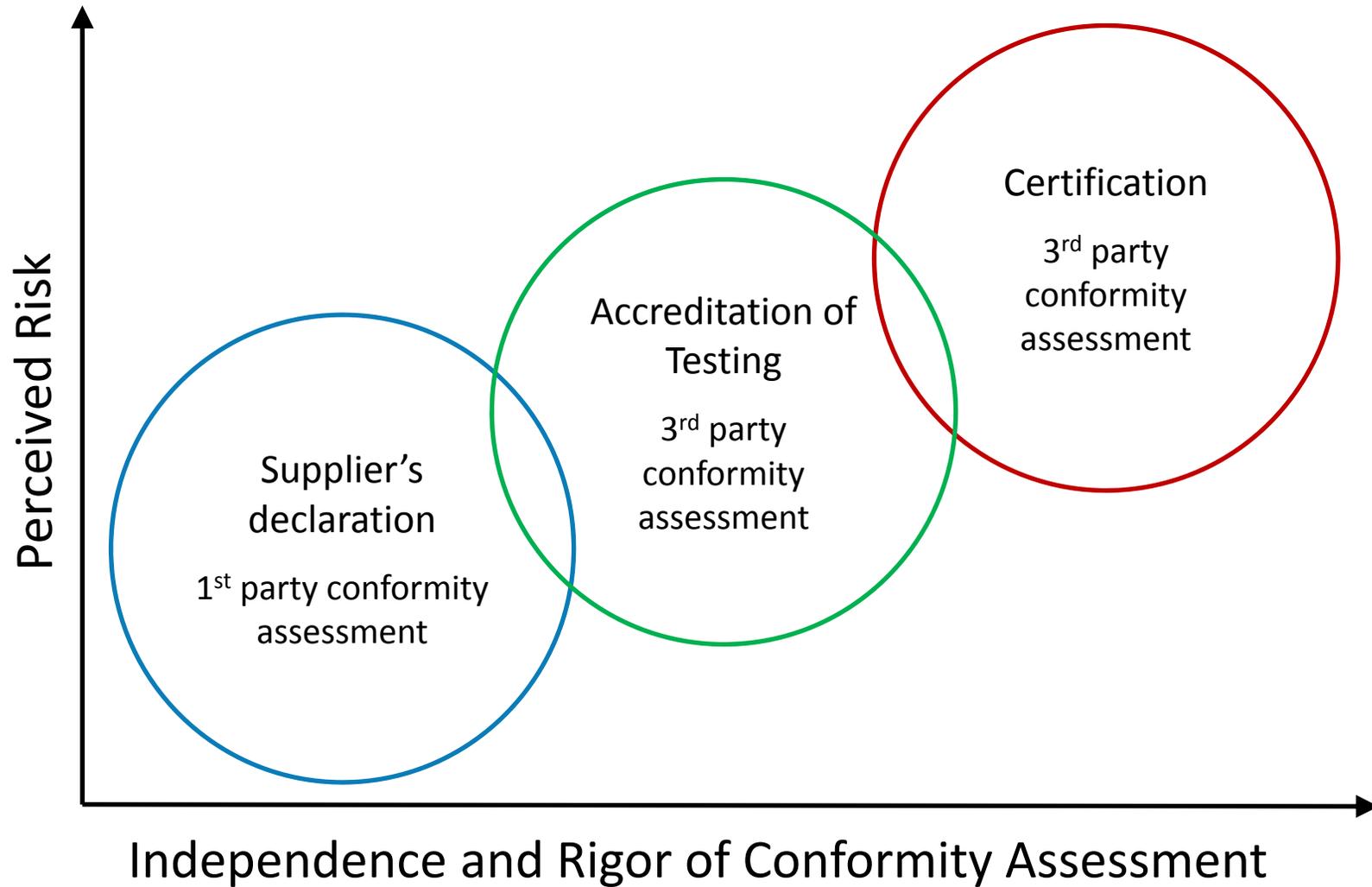


NIST robotics standards are catalyzing U.S. manufacturing transformation

Hazard Identification and Risk Assessment



How much confidence is needed?

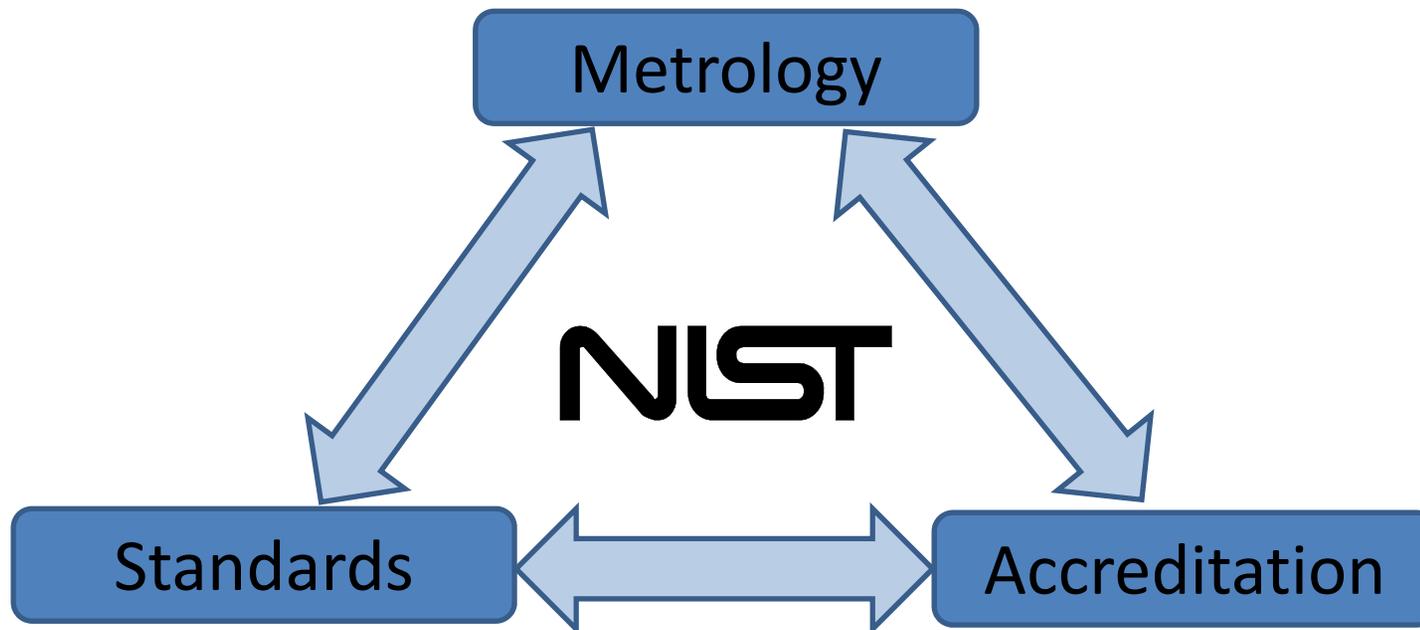


How much confidence is needed?

	SDoC	Testing	Inspection	Certification	Management System Certification
Arrangements	N/A	Mutual Recognition Arrangement	Mutual Recognition Arrangement	Multilateral Recognition Arrangement	Multilateral Recognition Arrangement
Accreditation	N/A	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)
Standard	ISO/IEC 17050 – Part 1 ISO/IEC 17050 – Part 2	Testing & Calibration Labs (ISO/IEC 17025)	Inspection Bodies (ISO/IEC 17020)	Certification Bodies (ISO/IEC 17065)	Registrars (ISO/IEC 17021)

Source: NIST Special Publication 2000-01, Draft ABC's of Conformity Assessment

NIST's Roles in the US Quality Infrastructure



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Increase in COUNTERFEITING is due to...



GLOBALIZATION

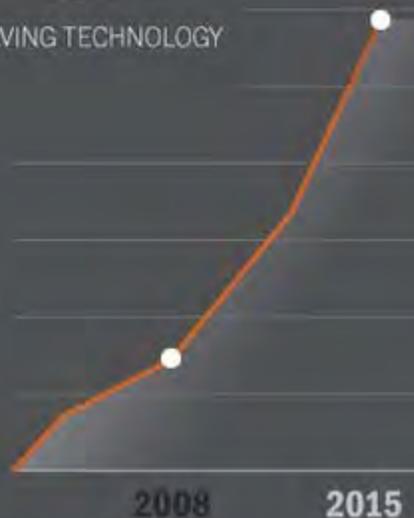
Total global economic value of counterfeit and pirated products was **\$650 billion** in 2008, and is expected to increase to **\$1.7 trillion** by 2015.



EVOLVING TECHNOLOGY



HIGH PROFITABILITY



Source: Frontier Economics study commissioned by ICC BASCAP

Consumer Electronics

recently became the top commodity seized at **22%**, a title previously held by **footwear** (9%) dating back to 2005.



Cell phones

accounted for approximately one third of counterfeit consumer electronics.



Certificates and Mandatory Third-Party Testing

Every manufacturer or importer of all consumer products must issue a general certificate of conformity based on testing of the product and stating that the product complies with the applicable standard, regulation, or ban.

The manufacturers or importers of children's products to certify that the products comply with all relevant product safety rules by issuing a certificate supported by tests performed by a CPSC-accepted third-party testing laboratory that has been accredited.

NISTIR 8118r1

A Guide to United States Electrical and Electronic Equipment Compliance Requirements

NIST
National Institute of
Standards and Technology
U.S. Department of Commerce

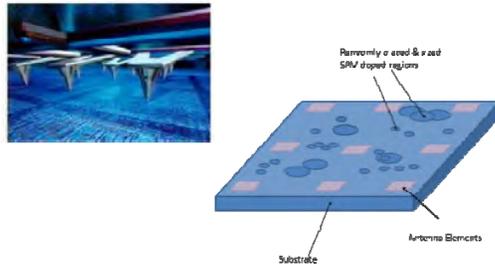
This publication is available free of charge from:

<https://doi.org/10.6028/NIST.IR.8118r1>

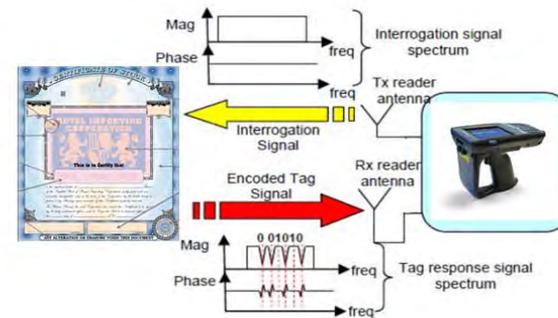
NIST
National Institute of
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U.S. Department of Commerce

Nano-structured Certificates of Authenticity

1. **CREATE:** Use probe arrays to create nanostructured CoAs

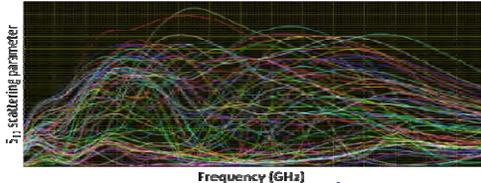


2. **READ:** Handheld scanners to interrogate CoAs.

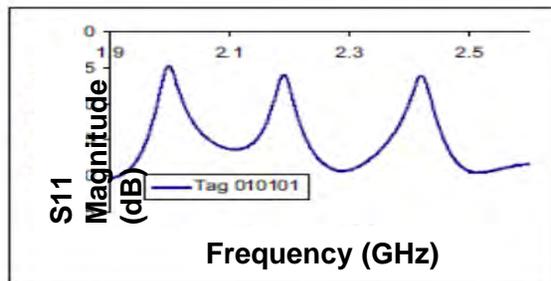


3. **VERIFY:** interpret and compare output

Raw data

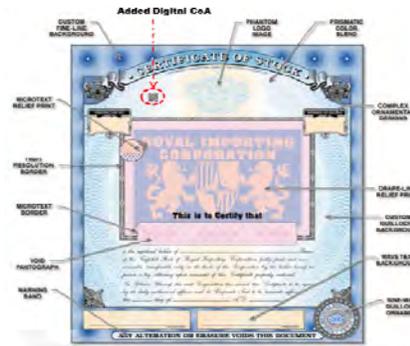


Data transform



GOOD – NO GOOD indicator

4. **SAMPLE PRODUCT FORM FACTORS**



Standards for Traceability and Authentication

- **SEMI T20-0710:** Specification for Authentication of Semiconductors and Related Products
- **SEMI T20.1-1109:** Specification for Object Labelling to Authenticate Semiconductors and Related Products in an Open Market
- **SEMI T20.2-1109:** Guide for Qualifications of Authentication Service Bodies for Detecting and Preventing Counterfeiting of Semiconductors and Related Products
- **SEMI T20.3-0710:** Specification for Service Communication for Authentication of Semiconductors and Related Products
- **SEMI T21-0212:** Specification for Organization Identification by Digital Certificate Issued from Certificate Service Body (CSB) for Anti-Counterfeiting Traceability in Components Supply Chain
- **SEMI T22-0212:** Specification for Traceability by Self Authentication Service Body and Authentication Service Body
- **ISO 16678:2014:** Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade.

<https://www.iso.org/obp/ui/#iso:std:iso:16678:ed-1:v1:en>

New ISO Standard In the Works

DRAFT INTERNATIONAL STANDARD
ISO/DIS 22380

ISO/DIS 22380:2017(E)

ISO/TC 292

Secretariat: SIS

Voting begins on:
2017-09-07

Voting terminates on:
2017-11-30

Security and resilience — Authenticity, integrity and trust for products and documents — General principles for product fraud risk

Sécurité et résilience — Titre manqué

ICS: 03.100.01

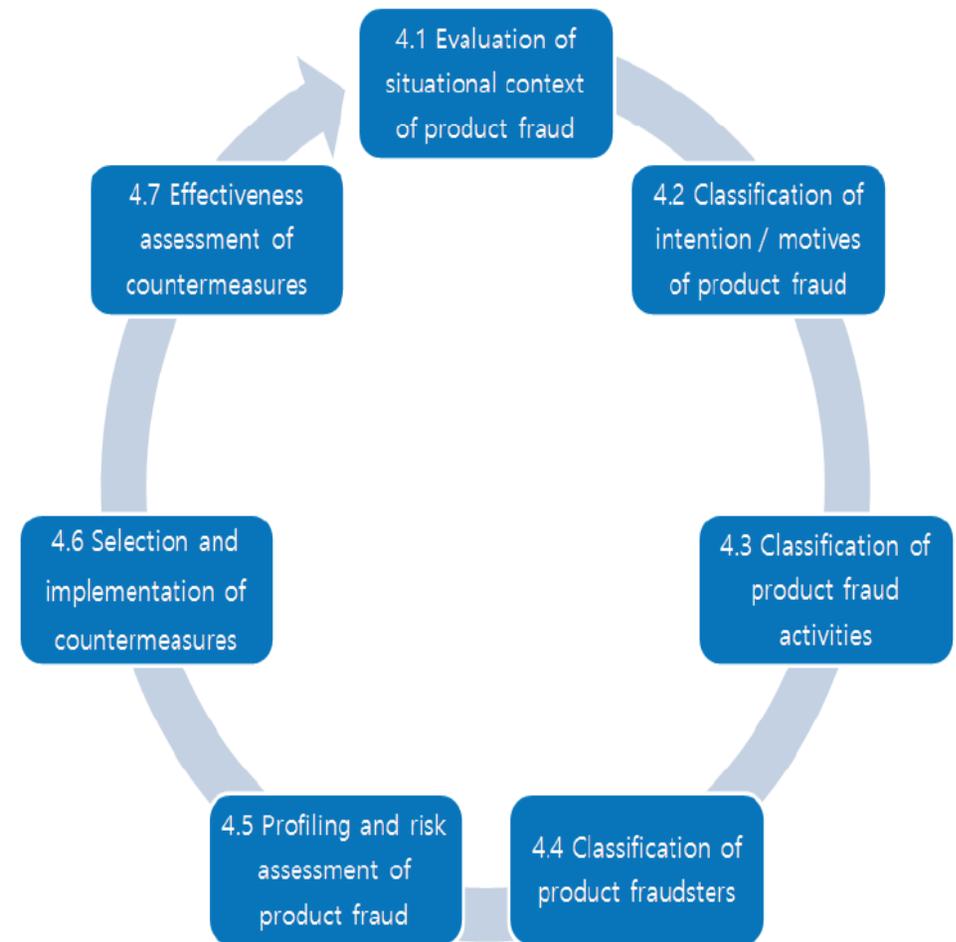
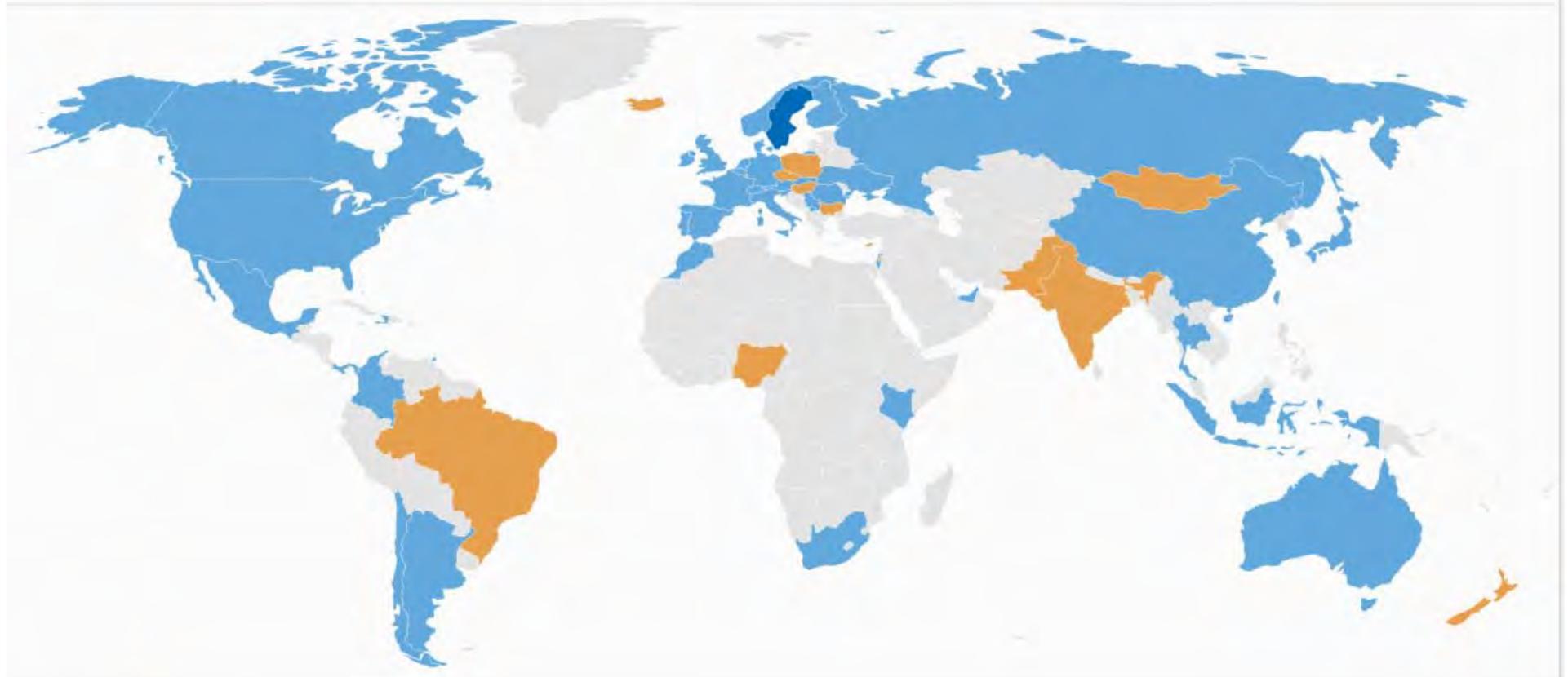


Figure 1 — The continual process of product fraud countermeasures and control strategy

ISO/TC 292

Security and resilience



Secretariat ■

Sweden - Swedish Standards Institute (SIS)

Participating Members (43) ■

Observing Members (15) ■

Take Home Messages...

- Conformity assessment does not have to be complicated or expensive.
 - The parties involved depends on the activities needed, related risks, and level or rigor required.
 - There are tools out there to help you
- ISO TC292 is developing standards to mitigate counterfeit products
 - SEMI has a suite of standards to mitigate counterfeit electronics
- But You Must Participate in the International Standards Setting Process!

My Contact Information

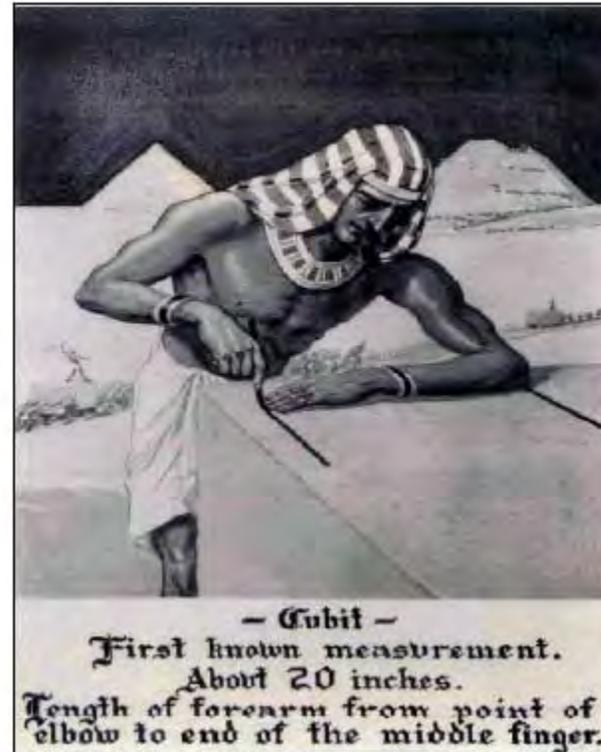
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What Can We Do Together?



Participants sing the African Union Anthem

